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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/997,850 | 11/29/2001 | Brian P. Brockway | 349.033US3 | 6258 |

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SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER

NASSER, ROBERT L

ART UNIT PAPER NUMBER

3736

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/997,850

Applicant(s)

BROCKWAY ET AL.

Examiner

Robert L. Nasser

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57-64,66-81 and 83-98 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 91-95 is/are allowed.
- 6) ☒ Claim(s) 57-64,66-81,83-90 and 96-98 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

The examiner regrets that upon further examination, a new reference was found that appears to be applicable to previously non-rejected claims 57-63, 65, 75, 77, 82, and 85. Accordingly, the following non-final rejection is being applied.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 69-80, 86, and 88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 69 recites that the catheter is of multi-durometer construction. This term is not defined in the specification. Applicant discloses a multi-durometer catheter, but it is unclear what makes it multi-durometer, considering that a durometer is a meter for measuring hardness. The examiner recognizes that applicant is entitled to define its own terminology. However, the burden is on applicant to make the scope of the terminology clear. The examiner cannot, as a result, determine the scope of the claim and therefore, no art is being applied to claims 69-80. The art rejection will be revisited upon resolution of the issue discussed above. In addition, Claims 70, 71, 86, and 88 recite that the catheter length is short enough to avoid significant head pressure artifact and provide sufficient dynamic response. They also recite that the length is long enough to accommodate surgical limitations and tolerance concerns. It is unclear what lengths are required for this to happen. Applicant has disclosed its desired range, but

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not at what lengths the artifacts become significant etc. In addition it is unclear what level of artifact is "significant" or what response is "sufficient." Clarification is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 57, 63, 64, and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Durand et al. Durand et al has a pressure transmitting catheter having a lumen entirely filled with a saline solution, which acts as a pressure transmitting medium. The transmitting catheter of Durand et al includes a first layer of material 1 made of a plastic surrounding the lumen, and a second material 4 of metal, having a differing hardness surrounding the first layer of material. Durand teaches that one end of the catheter connects to a pressure measuring catheter via connector 2, and that the second end connects to an instrument for measuring pressure. As such, the examiner notes that it is inherent that such instrument has a housing containing both a transducer and signal processing circuitry for processing the transducer output.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 58, 60, and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durand et al in view of Iwata et al. Durand et al uses a saline solution as the pressure transmitting medium. Iwata et al uses a gel as the pressure transmitting medium to fill the entire catheter. From this teaching, it would have been obvious to modify Durand et al to use a gel, to simplify the overall design.

Claims 59, 61, 62, 67, and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durand et al in view of Brockway et al 4,846,191. With respect to claim 59, Brockway teaches an alternative pressure transmitting medium comprised of a gel and a fluid combination. Hence, it would have been obvious to modify Durand et al to use this medium, as it is merely the substitution of one known medium for another. With respect to claims 61, 62, 67, and 68, Brockway et al further teaches wirelessly transmitting the data to a remote location away from the patient. Such a set up allows for long term monitoring of a patient without a nurse being at bedside as well as keeps the bedside area free from wires. Hence, it would have been obvious to modify Durand et al to use a wireless telemeter, to allow for improved monitoring of the patient.

Claims 83, 84, and 96-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durand et al in view of Iwata et al and Brockway et al. 4,846,191. Durand et al uses a saline solution as the pressure transmitting medium. Iwata et al uses a gel as the pressure transmitting medium to fill the entire catheter. From this teaching, it would have been obvious to modify Durand et al to use a gel, to simplify the overall design. Brockway et al further teaches wirelessly transmitting the data to a remote location away from the patient. Such a set up allows for long term monitoring of a patient without a nurse being at bedside as well as keeps the bedside area free from wires. Hence, it would have been obvious to modify the above combination to use a wireless telemeter, to allow for improved monitoring of the patient.

Claims 85-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durand et al in view of Pohndorf et al. Durand teaches that the pressure transmitting catheter may connect to a measuring instrument of a transducer. Pohndorf et al shows a device where the pressure transmitting catheter connects to a transducer, which in turn has a wire extending through a catheter to a signal processing device. Such an arrangement allows the wireless to be protected from the external environment. Hence, it would have been obvious to modify Durand et al to use such a configuration, as it is merely the use of a well known configuration in the art.

Claims 89 and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durand et al in view of Pohndorf, as applied to claims 85-88 above, further in view of Brockway et al. 4,846,191. Brockway et al further teaches wirelessly transmitting the data to a remote location away from the patient. Such a set up allows for long term monitoring of a patient without a nurse being at bedside as well as keeps the bedside area free from wires. Hence, it would have been obvious to modify the above combination to use a wireless telemeter, to allow for improved monitoring of the patient.

Claims 91-95 are allowable. Claims 91-95 define over the art of record in that none of the art has the slidable plug, as claimed.

Applicant's arguments filed 10/27/2003 have been fully considered but they are not persuasive.

Applicant has asserted with respect to the 112, first paragraph rejection of claims 70, 71, 86, and 88, that one skilled in the art would be able to make and use the device based on the disclosure. The examiner disagrees. The burden is on applicant to define the ranges of what is considered to be a "significant" head pressure artifact and what is considered to be "long enough."

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The remaining arguments are considered moot in view of the new grounds of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Robert L. Nasser
Primary Examiner
Art Unit 3736

RLN
January 10, 2004

